

ASX ANNOUNCEMENT: 3 April 2012**BNC105 Phase I/II Ovarian Cancer Trial**

Open Briefing with CEO & MD Deborah Rathjen

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Bionomics (ASX: BNO) is a drug discovery and development company focused on new treatments for cancer and serious disorders of the central nervous system (CNS).

Market capitalisation: \$172 million

In this Open Briefing®, CEO & MD Deborah Rathjen discusses

- Phase I/II clinical trial of BNC105 in women with ovarian cancer approved by FDA
- Update on Phase II BNC105 and Afinitor combination trials
- Commercialisation strategy and potential FDA fast-track designation for BNC105

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Bionomics Limited (ASX: BNO; ADR: BMICY) recently gained approval to proceed with a Phase I/II clinical trial of BNC105 in women with ovarian cancer. What is the significance of this for the development of BNC105?

CEO & MD Deborah Rathjen

Achieving this approval and making solid progress towards the initiation of this trial has been a major focus for our clinical development team over recent months. The trial forms an important strategic plank for Bionomics' BNC105 licensing ambitions and consistent with that strategy the trial will be conducted in Australia and the US. Data from both the renal and ovarian cancer trials would enable consideration by the FDA of fast-track designation for BNC105 adding substantial value to the BNC105 licensing package.

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Preclinical data recently presented at AACR demonstrates that BNC105 inhibits the proliferation of the human ovarian cancer cell line, A2780, and its cisplatin-resistant derivative, A2780cis. How has the preclinical data affected the planned structure of the clinical trials?

CEO & MD Deborah Rathjen

The preclinical data shows that BNC105 exerted a potent inhibitory activity on platinum resistant cancer cells in culture as well as reduced tumour size and improved survival in animals carrying platinum resistant ovarian cancers. This has given Bionomics a lot of confidence to set up this clinical trial. This robust data has also led Bionomics to consider the evaluation of BNC105 in women who are only somewhat sensitive to platinum-based treatment. The trial will therefore evaluate BNC105 in combination with two standard-of-care treatments, carboplatin and gemcitabine, in women whose disease progresses four to nine months following initial treatment with a platinum-based therapy. In this trial, we are also building on animal data which shows that BNC105 synergises with platinum-based therapies in bringing about an enhanced anti-cancer activity as measured by reduction in tumour size and improved survival.

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Why have you focused on ovarian cancer?

CEO & MD Deborah Rathjen

There is a clear unmet medical need for more effective systemic therapy. Despite modest improvements in patient outcomes as a result of surgery or platinum-based chemotherapy, the majority of ovarian cancer patients relapse and die of their disease.

The impetus to focus on ovarian cancer as a clinical trial setting for BNC105 came from the preclinical data. The data showed firstly, a strong synergy of BNC105 with a class of cancer chemotherapy drugs called platins which are based on platinum and secondly, that BNC105 was effective and in fact very potent, in killing platin resistant as well as platin sensitive ovarian cancer cells in culture. Platinum-based drugs are used as part of the standard-of-care in the treatment of ovarian cancer, however, resistance to platinum-based therapy can develop quickly and both sets of data point to the potential of BNC105 in this setting.

Ovarian cancer is the seventh leading cause of cancer-related death among Australian women. It is often diagnosed at an advanced stage after the cancer has spread beyond the ovary. In 2008 in Australia 1,272 ovarian cancer cases were diagnosed. The number of ovarian cancer cases in Australia increased by 47 percent between 1982 and 2006. It is anticipated that the number of new cases will continue to increase, with an estimated 1,488 women expected to be diagnosed with ovarian cancer in 2015. In 2010 there were an estimated 21,880 new cases and 13,850 deaths from ovarian cancer in the US. It is estimated that approximately US\$2.2 billion is spent in the US each year on treating ovarian cancer.

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How relevant will the trials be for BNC105's potential application to other types of cancer?

CEO & MD Deborah Rathjen

Looking beyond ovarian cancer to the broader potential of BNC105, the platins include cisplatin and carboplatin. They are used in the treatment of a broad range of solid tumour types including lung, prostate, breast, melanoma and mesothelioma, hence the importance of combining BNC105 with these drugs as we are doing in the ovarian cancer trial. The strategy is similar to choosing to combine BNC105 with Afinitor, an mTOR inhibitor, in the renal trial where BNC105 has the potential to represent an entirely new treatment paradigm for solid tumours.

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Could you outline the competition for BNC105?

CEO & MD Deborah Rathjen

BNC105 is unique amongst vascular disrupting agents (VDAs) in having been identified on the basis of its highly selective targeting of cancer blood vessels within solid tumours. The collapse of tumour blood vessels induced by BNC105 is very rapid and it does not affect normal blood vessels. This selectivity for tumour blood vessels is unique to BNC105 and is not shared by Ombrabulin (sanofi aventis) or Zybrestat (OxiGene).

Avastin (Roche/Genentech) which was recently approved in Australia for the treatment of ovarian cancer, targets newly forming cancer blood vessels (a process known as angiogenesis) but does not have any direct effect on cancer cells. By contrast BNC105 targets both newly forming and established blood vessels within solid tumour masses and in addition it exerts a potent, direct cytotoxic action on cancer cells. These latter features give BNC105 several potential competitive advantages over Avastin which is a blockbuster drug with reported sales in excess of US\$5.8 billion in 2011. Bionomics has undertaken several animal studies which indicate that BNC105 is able to synergise with Avastin and Bionomics views this latest approval for Avastin as positive for BNC105 since it indicates that a vascular targeting approach can yield clinical benefit for women with ovarian cancer.

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BNC105 is also undergoing a Phase II clinical trial, in combination with Afinitor, in patients with metastatic renal cell carcinoma (RCC, a form of kidney cancer). Can you update us on the trial's progress and the timeline for completion?

CEO & MD Deborah Rathjen

This is a US multi-centre clinical trial. Afinitor is an mTOR inhibitor, which is used as a second line treatment after patients have failed first line therapy with tyrosine kinase inhibitors (TKI). Afinitor, which was approved by the FDA for the treatment of renal cancer in 2009 and is marketed by global pharma company Novartis, had sales of US\$443 million in the year ended 31 December 2011, an increase of 80 percent on the previous year. Yet, there is always room for better treatment regimens and our hope is that BNC105 will prove to be the next breakthrough.

In October last year we indicated that the trial had reached an important milestone when the combination of Afinitor at its recommended dose and BNC105 at 16mg/m² had been shown to be safe and well tolerated. Plasma pharmacokinetic analysis of drug levels indicated no interaction between BNC105 and Afinitor, confirming the compatibility of the drug combination, unlike other vascular targeting agents which have not combined well with Afinitor. As a further indicator of the tolerability of the combination, individual patients within this part of the trial have received up to 15 cycles of treatment with the BNC105/Afinitor combination. Consequently the trial continued with expanded recruitment across a larger number of clinical sites. Recruitment of patients in over 30 clinical sites currently aims to complete enrolment of 134 patients by the end of 2012.

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You've indicated that data from this trial, together with the ovarian cancer trial, may enable FDA fast-track designation for BNC105. What are the key factors in achieving this designation? What would it mean for your BNC105 commercialisation strategy?

CEO & MD Deborah Rathjen

Bionomics is now targeting three cancer indications with BNC105 - metastatic renal cell cancer, ovarian cancer and mesothelioma. Like many forms of cancer these are serious illnesses for which there is a clear need for new treatment approaches. This is the key criterion for consideration for FDA fast-track designation. The FDA fast-track is a process designed to facilitate the development, and speed up the review, of drugs to treat serious diseases and fill an unmet medical need. The purpose is to get important new drugs to the patient and thus the market earlier. Path to market is obviously an important commercial consideration for any potential licensee and we believe that the BNC105 clinical trial program achieves the appropriate balance between path to market as well as broader demonstration of the commercial potential of the molecule.

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Thank you Deborah.

For more information about Bionomics Limited, visit www.bionomics.com.au or call Dr Deborah Rathjen on +61 8 8354 6101.

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ABOUT BIONOMICS LIMITED: Bionomics (ASX: BNO) is a leading international biotechnology company which discovers and develops innovative therapeutics for cancer and diseases of the central nervous system. Bionomics has small molecule product development programs in the areas of cancer, anxiety, epilepsy and multiple sclerosis. BNC105, which is undergoing clinical development for the treatment of cancer, is based upon the identification of a novel compound that potently and selectively restricts blood flow within tumours. A clinical program is also underway for the treatment of anxiety disorders and depression based on BNC210 which exhibits strong anxiolytic and anti-depression activity without side effects in preclinical models. Both compounds offer blockbuster potential if successfully developed. Bionomics' discovery and development activities are driven by its three technology platforms: Angene®, a drug discovery platform which incorporates a variety of genomics tools to identify and validate novel angiogenesis targets (involved in the formation of new blood vessels). MultiCore® is Bionomics' proprietary, diversity orientated chemistry platform for the discovery of small molecule drugs. ionX® is a set of novel technologies for the identification of drugs targeting ion channels for diseases of the central nervous system.